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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

MALLINCKRODT LLC, MALLINCKRODT INC., and DEPOMED, INC. Plaintiffs, v. ACTAVIS LABORATORIES FL, INC. Defendant.	Civil Action No. No. 2:15-cv-03800-KSH-CLW

AMENDED COMPLAINT

Plaintiffs Mallinckrodt LLC, Mallinckrodt Inc. (collectively and individually, "Mallinckrodt") and Depomed Inc. (together with Mallinckrodt, collectively "Plaintiffs"), by their undersigned attorneys, for their Amended Complaint against Defendant Actavis Laboratories FL, Inc. ("Actavis" or "Defendant"), herein allege:

NATURE OF ACTION

1. This is an action for patent infringement under the patent laws of the United States, Title 35 of the United States Code, arising from Actavis filing an Abbreviated New Drug Application ("ANDA") with the United States Food and Drug Administration ("FDA") seeking

approval to market generic versions of Plaintiffs' pharmaceutical product XARTEMIS™ XR prior to the expiration of United States Patent Nos. 8,597,681 ("the '681 patent"); 8,658,631 ("the '631 patent"); 8,741,885 ("the '885 patent"); 8,980,319 ("the '319 patent"); 8,992,975 ("the '975 patent); 7,976,870 ("the '870 patent"); 8,668,929 ("the '929 patent"); 8,372,432 ("the '432 patent"); 8,377,453 ("the '453 patent"); 8,394,408 ("the '408 patent"); and 9,050,335 ("the '335 patent").

PARTIES

2. Plaintiff Mallinckrodt LLC is a limited liability company organized and existing under the laws of the State of Delaware, having a place of business at 675 McDonnell Boulevard, Hazelwood, Missouri 63042-2379.

3. Plaintiff Mallinckrodt Inc. is a corporation organized and existing under the laws of the State of Delaware, having a place of business at 675 McDonnell Boulevard, Hazelwood, Missouri 63042-2379.

4. Plaintiff Depomed, Inc. ("Depomed") is a corporation organized and existing under the laws of the State of California, having a place of business at 7999 Gateway Blvd., Suite 300, Newark, CA 94560.

5. On information and belief, Defendant Actavis Laboratories FL, Inc., is a company organized and existing under the laws of the State of Florida with a principal place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, NJ 07054. On information and belief, Actavis is in the business of selling generic pharmaceutical products, which it distributes in the State of New Jersey and throughout the United States.

6. On information and belief, Actavis has previously submitted to the jurisdiction of this Court and has purposefully availed itself of the jurisdiction of this Court by filing lawsuits

and/or asserting counterclaims in lawsuits filed in the United States District Court for the District of New Jersey.

JURISDICTION AND VENUE

7. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

8. This Court has personal jurisdiction over Actavis by virtue of, inter alia, it having corporate presence in New Jersey, having conducted business in New Jersey, having availed itself of the rights and benefits of New Jersey law, previously consenting to personal jurisdiction in this Court, availing itself of the jurisdiction of this Court, and having engaged in systematic and continuous contacts with the State of New Jersey.

9. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391 and 1400(b).

XARTEMIS™ XR

10. XARTEMIS™ XR is an extended release tablet for oral administration. XARTEMIS™ XR contains the active ingredients oxycodone hydrochloride and acetaminophen. The recommended dose of XARTEMIS™ XR is one dose every 12 hours without regard to the patients' fed state. XARTEMIS™ XR is indicated for the management of acute pain severe enough to require opioid treatment and for which alternative treatment options are inadequate.

11. XARTEMIS™ XR combines an opioid analgesic agent with a non-opioid analgesic agent. XARTEMIS™ XR provides the advantage of additive and synergistic analgesic effects allowing for a lower dose of opioid, fewer side effects, and the ability to treat a broader spectrum of pain or pain states due to the different mechanisms of actions.

12. Previously marketed drug products delivered the combination drugs as an immediate release product.

13. This limitation required the drug product to be administered frequently and/or continuously throughout the day (or night) for continuous pain management. This frequent and/or continuous dosing is often inconvenient and difficult to maintain. Regular dosing is, therefore, inconvenient and frequently leads to poor patient compliance – potentially resulting in a dose being taken after pain breaks through, causing unnecessary pain and suffering.

14. During drug development, it was surprisingly discovered that a pharmaceutically acceptable gastric retentive dosage form can be formulated to provide release in the stomach of a combination of a sparingly soluble drug and a highly soluble drug at rates proportional to one another over an extended period of time.

15. In 2008, Mallinckrodt licensed from Depomed patents, a patent application, and know-how and subsequent to completion of drug product development Mallinckrodt sought approval from the FDA to market XARTEMIS™ XR in the United States. The FDA approved Mallinckrodt's New Drug Application No. 204031 ("the XARTEMIS™ XR NDA") for oxycodone hydrochloride and acetaminophen extended-release tablets, under the trade name XARTEMIS™ XR, on March 11, 2014.

16. As a part of the regulatory process for obtaining approval of the XARTEMIS™ XR NDA, Mallinckrodt was required by the FDA to submit a proposed label for the drug. See 21 C.F.R. § 201.56(b). The label for XARTEMIS™ XR instructs physicians and patients, inter alia, about the proper dosage and administration of XARTEMIS™ XR.

17. The label for XARTEMIS™ XR indicates, inter alia, that one dose of XARTEMIS™ XR is recommended twice daily.

18. A physician familiar with the use of extended-release tablets for the management of acute pain such as XARTEMIS™ XR would therefore understand that administration of an

opioid analgesic combined with a non-opioid analgesic agent would be subject to the label's instruction to administer a dose twice daily.

19. Plaintiffs have educated prescribing physicians regarding the use of XARTEMIS™ XR. Physicians are informed that the recommended dose of XARTEMIS™ XR is one dose every 12 hours. Physicians are told that the second dose may be administered as early as 8 hours after the initial dose if patients require analgesia at that time. Subsequent doses are to be administered every 12 hours. Further, on information and belief, it is the standard of care for physicians to treat acute pain in a manner that prevents pain break through. One or more claims of the patents in suit cover the method of treating pain by administering oxycodone hydrochloride and acetaminophen extended-release every 8-12 hours or twice daily.

THE PATENTS-IN-SUIT

20. On December 3, 2013, the United States Patent and Trademark Office issued the '681 patent, entitled "Methods of producing stabilized solid dosage pharmaceutical compositions containing morphinans." The '681 patent was assigned to Mallinckrodt by inventors Jae Han Park, Tiffani Eisenhauer, Anish Dhanarajan, Vishal K. Gupta, and Stephen Overholt. A copy of the '681 patent is attached hereto as Exhibit A.

21. On February 25, 2014, the United States Patent and Trademark Office issued the '631 patent, entitled "Combination composition comprising oxycodone and acetaminophen for rapid onset and extended duration of analgesia." The '631 patent was assigned to Mallinckrodt by inventors Krishna Devarakonda, Michael J. Guiliani, Vishal K. Gupta, Ralph A. Heasley, and Susan Shelby. A copy of the '631 patent is attached hereto as Exhibit B.

22. On June 3, 2014, the United States Patent and Trademark Office issued the '885 patent, entitled "Gastric retentive extended release pharmaceutical compositions." The '885

patent was assigned to Mallinckrodt by inventors Krishna Devarakonda, Michael J. Guiliani, Vishal K. Gupta, Ralph A. Heasley, and Susan Shelby. A copy of the ’885 patent is attached hereto as Exhibit C.

23. On March 17, 2015, the United States Patent and Trademark Office issued the ’319 patent, entitled “Methods of producing stabilized solid dosage pharmaceutical composition containing morphinans.” The ’319 patent was assigned to Mallinckrodt by inventors Jae Han Park, Tiffani Eisenhauer, Anish Dhanarajan, Vishal Gupta, and Stephen Overholt. A copy of the ’319 patent is attached hereto as Exhibit D.

24. On December 3, 2013, the United States Patent and Trademark Office issued the ’975 patent, entitled “Methods of producing stabilized solid dosage pharmaceutical compositions containing morphinans.” The ’975 patent was assigned to Mallinckrodt by inventors Jae Han Park, Tiffani Eisenhauer, Anish Dhanarajan, Vishal K. Gupta, and Stephen Overholt. A copy of the ’975 patent is attached hereto as Exhibit E.

25. On July 12, 2011, the United States Patent and Trademark Office issued the ’870 patent, entitled “Gastric retentive oral dosage form with restricted drug release in the lower gastrointestinal tract.” The ’870 patent was assigned to Depomed, Inc. by inventors Bret Berner, John W. Shell, and Jenny Louie-Helm. Depomed, Inc. granted Mallinckrodt an exclusive license under the ’870 patent with respect to, inter alia, oxycodone hydrochloride and acetaminophen extended release products known as XARTEMIS™ XR. A copy of the ’870 patent is attached hereto as Exhibit F.

26. On March 11, 2014, the United States Patent and Trademark Office issued the ’929 patent, entitled “Gastric retentive extended-release dosage forms comprising combinations of a non-opioid analgesic and an opioid analgesic.” The ’929 patent was assigned to Depomed

by inventors Chien-Hsuan Han, Sui Yuen Eddie Hou, and Monica L. Reid. Depomed granted Mallinckrodt an exclusive license under the ’929 patent with respect to, inter alia, oxycodone hydrochloride and acetaminophen extended release products known as XARTEMIS™ XR. A copy of the ’929 patent is attached hereto as Exhibit G.

27. On February 12, 2013, the United States Patent and Trademark Office issued the ’432 patent, entitled “Gastric retentive extended-release dosage forms comprising combinations of a non-opioid analgesic and an opioid analgesic.” The ’432 patent was assigned to Depomed by inventors Chien-Hsuan Han, Sui Yuen Eddie Hou, and Monica L. Reid. Depomed granted Mallinckrodt an exclusive license under the ’432 patent with respect to, inter alia, oxycodone hydrochloride and acetaminophen extended release products known as XARTEMIS™ XR. A copy of the ’432 patent is attached hereto as Exhibit H.

28. On February 19, 2013, the United States Patent and Trademark Office issued the ’453 patent, entitled “Gastric retentive extended-release dosage forms comprising combinations of a non-opioid analgesic and an opioid analgesic.” The ’453 patent was assigned to Depomed by inventors Chien-Hsuan Han, Sui Yuen Eddie Hou, and Monica L. Reid. Depomed granted Mallinckrodt an exclusive license under the ’453 patent with respect to, inter alia, oxycodone hydrochloride and acetaminophen extended release products known as XARTEMIS™ XR. A copy of the ’453 patent is attached hereto as Exhibit I.

29. On March 12, 2013, the United States Patent and Trademark Office issued the ’408 patent, entitled “Gastric retentive extended-release dosage forms comprising combinations of a non-opioid analgesic and an opioid analgesic.” The ’408 patent was assigned to Depomed by inventors Chien-Hsuan Han, Sui Yuen Eddie Hou, and Monica L. Reid. Depomed granted Mallinckrodt an exclusive license under the ’408 patent with respect to, inter alia, oxycodone

hydrochloride and acetaminophen extended release products known as XARTEMIS™ XR. A copy of the ’408 patent is attached hereto as Exhibit J.

30. On June 9, 2015, the United States Patent and Trademark Office issued the ’335 patent, entitled “Pharmaceutical compositions for extended release of oxycodone and acetaminophen resulting in a quick onset and prolonged period of analgesia.” The ’335 patent was assigned to Mallinckrodt by inventors Krishna Devarakonda, Michael J. Guiliani, Vishal K. Gupta, Ralph A. Heasley, and Susan Shelby. A copy of the ’335 patent is attached hereto as Exhibit K.

31. Each of the foregoing patents are listed for XARTEMIS™ XR in the Patent and Exclusivity Information Addendum of the FDA’s publication Approved Drug Products with Therapeutic Equivalence Evaluations (“the Orange Book”). The Patent Use Codes listed in the Orange Book for the XARTEMIS™ XR product are “Method of Treating Patients with Gastric Retentive Dosage Form” and “Management of Acute Pain in Patients Requiring Opioid Analgesia.”

ACTAVIS’S ANDA

32. On information and belief, Actavis submitted ANDA No. 207113 (“the Actavis ANDA”) to the FDA, pursuant to 21 U.S.C. § 355(j), seeking approval to market oxycodone hydrochloride and acetaminophen extended-release tablets before the expiration of the patents in suit. The oxycodone hydrochloride and acetaminophen extended-release tablets described in the Actavis ANDA are herein referred to as the “Actavis Product.”

33. The Actavis ANDA refers to and relies upon the XARTEMIS™ XR NDA and contains data that, according to Actavis, demonstrates the bioequivalence of the Actavis Product and XARTEMIS™ XR.

34. On or about April 24, 2015, Plaintiffs received Defendant's letter (the "Actavis Notification") stating that Actavis had included a certification in the Actavis ANDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), that the patents in suit are invalid or will not be infringed by the commercial manufacture, use, or sale of the Actavis Product (the "Actavis Paragraph IV Certification"). On or about September 3, 2015, Actavis sent Defendants a second notice letter stating that Actavis had included a certification in the Actavis ANDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), that the '335 patent is invalid or will not be infringed by the commercial manufacture, use, or sale of the Actavis Product.

COUNT I
ACTAVIS'S DIRECT INFRINGEMENT OF U.S. PATENT NO. 8,597,681 UNDER
35 U.S.C. § 271(e)(2)(A)

35. Plaintiffs reallege and incorporate by reference the allegations of paragraphs 1-34 of this Complaint.

36. Actavis has infringed the '681 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting the Actavis ANDA, by which Actavis seeks approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale, or importation of the Actavis Product prior to the expiration of the '681 patent.

37. Plaintiffs will be substantially and irreparably harmed if Actavis is not enjoined from infringing the '681 patent.

38. Plaintiffs have no adequate remedy at law.

COUNT II
ACTAVIS'S DIRECT INFRINGEMENT OF U.S. PATENT NO. 8,658,631 UNDER
35 U.S.C. § 271(e)(2)(A)

39. Plaintiffs reallege and incorporate by reference the allegations of paragraphs 1-38 of this Complaint.

40. Actavis has infringed the ’631 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting the Actavis ANDA, by which Actavis seeks approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale, or importation of the Actavis Product prior to the expiration of the ’631 patent.

41. Plaintiffs will be substantially and irreparably harmed if Actavis is not enjoined from infringing the ’631 patent.

42. Plaintiffs have no adequate remedy at law.

COUNT III
ACTAVIS’S DIRECT INFRINGEMENT OF U.S. PATENT NO. 8,741,885 UNDER 35 U.S.C. § 271(e)(2)(A)

43. Plaintiffs reallege and incorporate by reference the allegations of paragraphs 1-42 of this Complaint.

44. Actavis has infringed the ’885 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting the Actavis ANDA, by which Actavis seeks approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale, or importation of the Actavis Product prior to the expiration of the ’885 patent.

45. Plaintiffs will be substantially and irreparably harmed if Actavis is not enjoined from infringing the ’885 patent.

46. Plaintiffs have no adequate remedy at law.

COUNT IV
ACTAVIS’S DIRECT INFRINGEMENT OF U.S. PATENT NO. 8,980,319 UNDER 35 U.S.C. § 271(e)(2)(A)

47. Plaintiffs reallege and incorporate by reference the allegations of paragraphs 1-46 of this Complaint.

48. Actavis has infringed the ’319 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by

submitting the Actavis ANDA, by which Actavis seeks approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale, or importation of the Actavis Product prior to the expiration of the ’319 patent.

49. Plaintiffs will be substantially and irreparably harmed if Actavis is not enjoined from infringing the ’319 patent.

50. Plaintiffs have no adequate remedy at law.

COUNT V
ACTAVIS’S DIRECT INFRINGEMENT OF U.S. PATENT NO. 8,992,975 UNDER 35 U.S.C. § 271(e)(2)(A)

51. Plaintiffs reallege and incorporate by reference the allegations of paragraphs 1-50 of this Complaint.

52. Actavis has infringed the ’975 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting the Actavis ANDA, by which Actavis seeks approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale, or importation of the Actavis Product prior to the expiration of the ’975 patent.

53. Plaintiffs will be substantially and irreparably harmed if Actavis is not enjoined from infringing the ’975 patent.

54. Plaintiffs have no adequate remedy at law.

COUNT VI
ACTAVIS’S DIRECT INFRINGEMENT OF U.S. PATENT NO. 7,976,870 UNDER 35 U.S.C. § 271(e)(2)(A)

55. Plaintiffs reallege and incorporate by reference the allegations of paragraphs 1-54 of this Complaint.

56. Actavis has infringed the ’870 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting the Actavis ANDA, by which Actavis seeks approval from the FDA to engage in the

commercial manufacture, use, offer to sell, sale, or importation of the Actavis Product prior to the expiration of the ’870 patent.

57. Plaintiffs will be substantially and irreparably harmed if Actavis is not enjoined from infringing the ’870 patent.

58. Plaintiffs have no adequate remedy at law.

COUNT VII
ACTAVIS’S DIRECT INFRINGEMENT OF U.S. PATENT NO. 8,668,929 UNDER 35 U.S.C. § 271(e)(2)(A)

59. Plaintiffs reallege and incorporate by reference the allegations of paragraphs 1-58 of this Complaint.

60. Actavis has infringed the ’929 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting the Actavis ANDA, by which Actavis seeks approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale, or importation of the Actavis Product prior to the expiration of the ’929 patent.

61. Plaintiffs will be substantially and irreparably harmed if Actavis is not enjoined from infringing the ’929 patent.

62. Plaintiffs have no adequate remedy at law.

COUNT VIII
ACTAVIS’S DIRECT INFRINGEMENT OF U.S. PATENT NO. 8,372,432 UNDER 35 U.S.C. § 271(e)(2)(A)

63. Plaintiffs reallege and incorporate by reference the allegations of paragraphs 1-62 of this Complaint.

64. Actavis has infringed the ’432 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting the Actavis ANDA, by which Actavis seeks approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale, or importation of the Actavis Product prior to

the expiration of the ’432 patent.

65. Plaintiffs will be substantially and irreparably harmed if Actavis is not enjoined from infringing the ’432 patent.

66. Plaintiffs have no adequate remedy at law.

COUNT IX
ACTAVIS’S DIRECT INFRINGEMENT OF U.S. PATENT NO. 8,377,453 UNDER
35 U.S.C. § 271(e)(2)(A)

67. Plaintiffs reallege and incorporate by reference the allegations of paragraphs 1-66 of this Complaint.

68. Actavis has infringed the ’453 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting the Actavis ANDA, by which Actavis seeks approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale, or importation of the Actavis Product prior to the expiration of the ’453 patent.

69. Plaintiffs will be substantially and irreparably harmed if Actavis is not enjoined from infringing the ’453 patent.

70. Plaintiffs have no adequate remedy at law.

COUNT X
ACTAVIS’S DIRECT INFRINGEMENT OF U.S. PATENT NO. 8,394,408 UNDER
35 U.S.C. § 271(e)(2)(A)

71. Plaintiffs reallege and incorporate by reference the allegations of paragraphs 1-70 of this Complaint.

72. Actavis has infringed the ’408 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting the Actavis ANDA, by which Actavis seeks approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale, or importation of the Actavis Product prior to the expiration of the ’408 patent.

73. Plaintiffs will be substantially and irreparably harmed if Actavis is not enjoined from infringing the ’408 patent.

74. Plaintiffs have no adequate remedy at law.

COUNT XI
ACTAVIS’S DIRECT INFRINGEMENT OF U.S. PATENT NO. 9,050,335 UNDER 35 U.S.C. § 271(e)(2)(A)

75. Plaintiffs reallege and incorporate by reference the allegations of paragraphs 1-74 of this Complaint.

76. Actavis has infringed the ’335 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting the Actavis ANDA, by which Actavis seeks approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale, or importation of the Actavis Product prior to the expiration of the ’335 patent.

77. Plaintiffs will be substantially and irreparably harmed if Actavis is not enjoined from infringing the ’335 patent.

78. Plaintiffs have no adequate remedy at law.

COUNT XII
EXCEPTIONAL CASE WITH RESPECT TO ACTAVIS UNDER 35 U.S.C. § 285

79. Plaintiffs reallege and incorporate by reference the allegations of paragraphs 1-78 of this Complaint.

80. Actavis alleges that eleven different patents duly examined by the U.S. Patent & Trademark Office are invalid or not infringed. This case is exceptional, and Plaintiffs should be granted award of attorneys’ fees under 35 U.S.C. § 285 in light of Actavis’s conduct.

PRAYER FOR RELIEF

WHEREFORE, Mallinckrodt Inc., Mallinckrodt LLC, and Depomed pray for a judgment in their favor and against Defendant Actavis Laboratories FL, Inc., and respectfully request the following relief:

A. A judgment declaring that Actavis has infringed U.S. Patent No. 8,597,681;

B. A judgment declaring that Actavis has infringed U.S. Patent No. 8,658,631;

C. A judgment declaring that Actavis has infringed U.S. Patent No. 8,741,885;

D. A judgment declaring that Actavis has infringed U.S. Patent No. 8,980,319;

E. A judgment declaring that Actavis has infringed U.S. Patent No. 8,992,975;

F. A judgment declaring that Actavis has infringed U.S. Patent No. 7,976,870;

G. A judgment declaring that Actavis has infringed U.S. Patent No. 8,668,929;

H. A judgment declaring that Actavis has infringed U.S. Patent No. 8,372,432;

I. A judgment declaring that Actavis has infringed U.S. Patent No. 8,377,453;

J. A judgment declaring that Actavis has infringed U.S. Patent No. 8,394,408;

K. A judgment declaring that Actavis has infringed U.S. Patent No. 9,050,335;

L. A judgment pursuant to 35 U.S.C. § 271(e)(4)(B) preliminarily and permanently enjoining Actavis, its officers, agents, servants, and employees, and those persons in active concert or participation with any of them, from manufacturing, using, offering to sell, or selling the Actavis Product within the United States, or importing the Actavis Product into the United States, prior to the expiration date of the patents in suit;

M. A judgment ordering that pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of ANDA No. 207113 under § 505(j) of the Federal Food, Drug and Cosmetic Act 21 U.S.C. § 355(j) shall not be earlier than the expiration date of the patents in suit, including any exclusivities and extensions;

N. If Actavis commercially manufactures, uses, offers to sell, or sells the Actavis

Product within the United States, or imports the Actavis Product into the United States, prior to the expiration of the patents in suit, including any exclusivities and extensions, a judgment awarding Plaintiffs monetary relief together with interest;

O. Attorneys' fees in this action as an exceptional case pursuant to 35 U.S.C. § 285.

P. Costs and expenses in this action; and

Q. Such other relief as the Court deems just and proper.

Dated: November 2, 2015

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